

Message Text

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ORIGIN HEW-06

INFO OCT-01 ARA-14 ISO-00 OES-07 MED-03 /031 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VB
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: MKEFAUVER
ARA/ECA:RGRAHAM(INFO)

-----064634 210226Z /64

R 201952Z MAR 78
FM SECSTATE WASHDC
TO AMEMBASSY MONTEVIDEO

UNCLAS STATE 071171

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, UY

SUBJECT: FDA ADVISORY - POSSIBLY DEFECTIVE MEDICAL DEVICE
(RECCAL-055-8)

1. FDA ADVISES OF THE FOLLOWING RECALL:
PRODUCT INVOLVED - OLYMPUS MODEL FB-14C BIOPSY FORCEPS;
PRODUCT IS A MINIATURE BIOPSY FORCEPS CONTAINED ON A
FLEXIBLE SHAFT.
PRODUCT IDENTIFICATION - (A) THE PLASTIC HANDLE OF THE
DEVICE CONTAINS A METAL LABEL WITH BLACK LETTERING READING
"OLYMPUS FB-14C JAPAN". THE HANDLE IS ADDITIONALLY HEAT
STAMPED WITH THE LOT NO. (B) THE LOT NUMBER CONSISTS OF A
FOUR OR FIVE DIGIT ALPHA NUMERIC CODE DECIPHERING THE DATE
OF MFR. THE FIRST DIGIT IS A MFR'S CONTROL LETTER. THE
LAST FOUR DIGITS ARE NUMBERS INDICATE THE RESPECTIVE YEAR
AND MONTH OF MFR, E.G. A779 - SEPT 1977. THE THREE LOTS
INVOLVED CONTAIN DIGITAL NUMBERS ENDING IN 779, 7710, AND
7711, CORRESPONDING TO SEPT, OCT, AND NOV 1977.

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2. REASON FOR RECALL: DURING AN INSPECTION ON 12/22/77
THE FIRM ADVISED FDA THAT THEY WERE ANTIICIPATING A RECALL
OF THE ABOVE PRODUCT. INVESTIGATION REVEALED THAT SOME
DEVICES IN THESE LOTS BORE MICROSCOPIC CRACKS IN THE FORCEPS
CUPS WHICH WHEN SUBJECTED TO EXCESS PRESSURE COULD DETACH.

IF THESE CUPS DETACH DURING USE, THEY COULD LODGE IN THE

ORGAN UNDERGOING ENDOSCOPY, I.E., THE LUNG, COLON, ETC. TESTS CONDUCTED BY THE MFR REVEALED THAT DEVICES IN THESE LOTS WERE FOUND TO FAIL WHEN SUBJECTED TO 5 TO 9 KG OF STRESS. MGT ADVISED THAT THE MFR HAD INSTITUTED MORE STRINGENT QUALITY CONTROL SPECIFICATIONS ON THEIR PRODUCTS WHEN IT WAS OBSERVED THAT SEVERAL DEVICES OF THE ABOVE 3 LOTS FAILED THESE STRESS TESTS. THE FIRM'S NEW SPECIFICATION IS 10 KG OF STRESS. THE FIRM EST THAT NORMAL BIOPSY PROCEDURES RQR 1-2 KG OF STRESS. THE PRODUCT IS A REUSABLE ITEM. THE FIRM HAS NOT RECEIVED ANY COMPLAINTS OR INJURIES ASSOCIATED WITH THIS MODEL OF BIOPSY FORCEPS. IN 9/76 THE FIRM HAD RECEIVED A COMPLAINT ON THEIR MODEL CFL B2 BIOPSY FORCEPS IN WHICH THE CUP DETACHED IN A PATIENT'S COLON AND WAS LATER EXCRETED. SUBSEQUENT FOLLOW-UP BY THE FIRM'S REPRESENTATIVE REVEALED THAT THIS PARTICULAR DEVICE HAD BEEN OTHERWISE DAMAGED.

3. ACTION - POST REQUESTED TO CONTACT DR. EDUARDO DESTEPHANIE, C/O DR. J.M. PINEYRO, OBLIGADO 965, APT. 601 MONTEVIDEO TO DETERMINE IF DR. DESTEPHANIE IS AWARE OF POSSIBLE DEFECT. IF DR.'S FB-14C BIOPSY FORCEPS IS FROM ONE OF AFFECTED LOTS IT IS "NOT TO BE USED EVEN IF NO REPLACEMENT ON HAND" BUT SHOULD BE RETURNED TO MFR. FOR REPLACEMENT. IF RECIPIENT HAS ANY QUESTIONS REQUEST THAT HE CONTACT MARKETING DEPARTMENT, MEDICAL INSTRUMENT DIVISION, OLYMPUS CORPORATION OF AMERICA, ATTENTION:
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KOJI MIYATA, ASSISTANT DIVISION MANAGER. VANCE

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL FACILITIES, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 20 mar 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE071171
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, MD:VB
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780123-0696
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780346/aaaabnaf.tel
Line Count: 95
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 5df260c3-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
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Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 08 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3266165
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - POSSIBLY DEFECTIVE MEDICAL DEVICE (RECCAL-055-8)
TAGS: OGEN, ETRD, EIND, TBIO, UY
To: MONTEVIDEO
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/5df260c3-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
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